

BiPAP Auto with BiFlex® as a rescue therapy for optimally treated obstructive sleep apnoea patients who demonstrate poor compliance to continuous positive airway pressure therapy

Submission date 05/11/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/12/2008	Overall study status Completed	☐ Protocol
Last Edited 14/11/2013	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Thibault Gentina

Contact details

Laboratoire du Sommeil
Clinique De La Louviere
69 Rue de la Louviere
59800
Lille
France
59800
t.gentina@wanadoo.fr

Additional identifiers

Protocol serial number

EAME06AUTOBILEVEL01

Study information

Scientific Title

Acronym

AUTOBILEVEL

Study objectives

BiPAP Auto with Bi-Flex® therapy will improve compliance, subjective sleepiness and quality of life in obstructive sleep apnoea patients who demonstrate poor compliance to standard fixed pressure therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Protection of Human Subjects in Biomedical Research (CCPPRB), Lille, 02/05/2006, ref: CP 06/57

Study design

Observational study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

After a full polysomnography (PSG) patients will be given a BiPAP Auto with Bi-Flex® device. Patients will be followed up at 15 days and 10 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

To determine whether rescuing optimally treated OSA patients who demonstrate poor compliance to PAP therapy by transitioning them onto BiPAP Auto with Bi-Flex improves compliance, subjective sleepiness and quality of life.

1. Compliance will be measured at 15 days and 10 weeks by retrieving device data
2. Subjective compliance and quality of life will be measured by Epworth Sleepiness Questionnaire and Functional Outcomes of Sleep Therapy questionnaire at baseline, 15 days and 10 weeks

Key secondary outcome(s)

1. Determination of comfort between BiPAP Auto with Bi-Flex® and previous device used. Measured by Device Comfort scale at baseline, 15 days and 10 weeks.
2. Identify barriers to successful transition onto BiPAP Auto with Bi-Flex®. Patients' previous machine type and mask will be noted and effect on transition assessed.
3. To determine the machine types used by patients who demonstrate poor compliance to fixed PAP therapy and their treatment efficacy during sleep. Previous machine type will be noted at baseline and treatment efficiency during baseline PSG.

Tertiary objective:

4. To investigate the level of agreement between Apnoea-Hypopnea Index (AHI) measured at Visit 1 (15 days) by PSG and an autotitrating PAP device in a subgroup of patients. Carried out at Visit 1 by PSG.

Completion date

26/02/2008

Eligibility**Key inclusion criteria**

1. Male and female patients 18+
2. Compliance to positive airway pressure (PAP) below the minimally acceptable level of 4 hours use on $\geq 70\%$ of nights over the past 4 weeks
3. Ability to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Wrong mask choice
2. Wrong mask size
3. Nasal congestion
4. Other symptoms requiring humidification

Date of first enrolment

21/08/2006

Date of final enrolment

26/02/2008

Locations

Countries of recruitment

France

Study participating centre

Laboratoire du Sommeil

Lille

France

59800

Sponsor information

Organisation

Respironics International Inc. (France)

ROR

<https://ror.org/05jz46060>

Funder(s)

Funder type

Industry

Funder Name

Respironics International Inc. (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration